Preferred Drug List Committee Meeting

Meeting Minutes, Open Session
March 11, 2020 11:30 a.m. to 1:00 p.m.
DXC Technologies-Capital Room, 6511 SE Forbes Ave., Bldg. 283 J, Topeka, Kansas 66619

Board Members Present: Wayne Wallace, M.D. William Pankey, M.D Katherine Grimsley, M.D Robert Haneke, Pharm.D. (Phone) Donna Sweet, M.D. (Phone) (Meeting Chair) Taylor Gill, Pharm.D., BCPS, (Phone)	**Board Members Absent:** Jessica Bates, Pharm.D., BCPS (Chair) James Rider, D.O. Emily Blew, Pharm.D. Megan Hedden, Pharm.D.
KDHE-DHCF Staff/Intern Present: Annette Grant, RPh Victor Nguyen, Pharm.D.	**KDHE-DHCF Staff Absent:** John Esslinger, M.D.
DXC/HID Staff Present: Kathy Kaesewurm, RN, BSN	**DXC/HID Staff Absent:** Karen Kluczykowski, RPh
MCO Attendees: Alan Carter, Pharm.D. – Aetna Better Health Kelley Courington Pharm.D. – Sunflower Health Plan Janette Mueller, RPh – United Healthcare	
Public Attendees: Rhonda Clark, Indivior; Sara Joyce, KDHE Pharmacy Intern; Brent Young, GBT; Dave Poskey, UCB; Doug Wood, Viiv HC; Dave Miley, Teva; Rhianna Tortorige, Abbott; Rob Hansen, Jim Baumann, Pfizer; Ricki Roberson, Merck; Bob Summers, Boehringer-Ingelheim; Brent Hildebrand, Gilead; Berend Koops, Merck. Illegible names not included.	

Item	Notes
I. Call to Order	The Chairperson, Dr. Bates, and Dr. Hedden who had been asked to fill the role as chairperson in Dr. Bates absent were both absent. Ms. Grant asked the board for volunteers to chair the meeting today in their absence. Dr. Sweet volunteered. Dr. Sweet called the March 11, 2020 PDL Committee meeting to order at 11:32 a.m. Dr. Sweet addressed the board members present and those attending by phone.
II. Review and Approval of September 11, 2019 Meeting Minutes.	The draft minutes from the September 11, 2019 meeting were reviewed. Ms. Grant informed the Board that the consent agenda items Appendix A had not been included when the document was emailed to the committee, but is included in the version presented today, for approval. Dr. Haneke moved to approve the minutes. Dr. Pankey seconded the motion. The motion carried unanimously, and the minutes were approved.
III. Old Business **A. Consent Agenda Items** **i. PDL New Drug Placements** 1. Arazlo™ Lotion 2. Conjupri® Tablets 3. Drizalma Sprinkle® 4. Harvoni® Pellets 5. Ipratropium Bromide 0.02% Inhalation Solution. 6. ProAir Digihaler® 7. RediTrex™ Injection 8. Riomet ER ™ Suspension 9. Solvaldi® Pellets 10. Zyrtec ODT/CT®	**Background:** At the September 13, 2017 PDL meeting, the Committee agreed to the "Consent Agenda Items" pre-management process and to place the associated drug list under the Old Business section. **Public Comment:** None. **Board Discussion:** Dr. Wallace moved to approve. Dr. Haneke seconded the motion. The motion carried unanimously.

Item	Notes
IV. New Business **A. New Drug Classes** **i. Acne Agents – Isotretinoin Products – (Absorica®, Absorica® LD, Accutane®, Amnesteem®, Claravis®, Myorisan®, Sotret®, Zenatane®)**	**Background:** This is a new class presented for inclusion to the PDL today. It includes the different formulations of the isotretinoin products used for severe recalcitrant nodular acne. Retinoids like isotretinoin products reduce sebaceous gland size and reduces sebum production in acne treatment. According to the 2016 Guidelines of care for the management of acne vulgaris from American Academy of Dermatology, presence of moderate acne that is either treatment-resistant, or that produces physical scarring of significant psychosocial distress, is an indication for treatment with oral isotretinoin. **Public Comment:** None. **Committee Discussion:** Dr. Sweet questioned the frequency of use of these types of products. Dr. Pankey responded that they are primarily prescribed by dermatologists rather than pediatricians. Dr. Sweet indicated that the statement in the Topic Introductions i. regarding neuroblastoma was unnecessary. Ms. Grant agreed that it was not needed, but had been included for completeness of information. Dr. Wallace moved to approve. Dr. Pankey seconded. The motion carried unanimously.

Item	Notes
ii. Colchicine Products – Prophylaxis – (Colcrys™, Gloperba®, Mitigare™)	**Background:** This is a new class presented for inclusion to the PDL today. It includes the different formulations of colchicine used for prophylaxis of acute gout flares. Colchicine disrupts cytoskeletal functions by inhibiting β- tubulin polymerization into microtubules, preventing activation, degranulation, and migration of neutrophil associated with mediating some gout symptoms. **Public Comment:** None. **Committee Discussion:** Dr. Sweet asked for clarification on the comparison table provided regarding the cost for generic colchicine. Dr. Nguyen clarified that the price listed for Colcrys was the price of the approved generic. Dr. Wallace moved to approve. Dr. Gill seconded. Motion carried unanimously.
iii. SGLT2 Inhibitor/DPP-4 Inhibitor/Biguanide Combination Agents – Oral – New Class: (Qternmet® XR, Trijardy™ XR)	**Background:** This is a new class presented for inclusion to the PDL today. It includes the different combinations of a sodium-glucose co-transporter 2 (SGLT2) inhibitor, Dipeptidyl peptidase-4 (DPP-4) inhibitor, and biguanide (Metformin) use for treatment of diabetes mellitus, type 2. According to American Diabetes Association (ADA) and American Association of Clinical Endocrinologist/American College of Endocrinology (AACE/ACE) guidelines, both suggest triple therapy (no specific drug regimen or length) as an option for patients that do not meet glycemic goal after trying individualized mono- and dual-therapies. Metformin is generally considered a first line pharmacological therapy. Generally, SGLT2 Inhibitors are recommended before DPP-4 Inhibitors, but the order is based upon specific patient factors. **Public Comment:** None. **Committee Discussion:** None.

Item	Notes
	Dr. Gill moved to approve. Dr. Wallace seconded. The motion was carried unanimously.
B. New Drugs to Existing Classes **i. Anti-Constipation Agents – Class Review – New Agent: (Motegrity™)**	**Background:** This class was last reviewed in June of 2017 and currently includes Amitiza®, Linzess®, and Trulance™. An oral selective serotonin (5-HT4) receptor agonist, Motegrity™ (pruclopride) was approved for the treatment of chronic idiopathic constipation (CIC) and is being presented for inclusion to the PDL. This drug will stimulate peristaltic reflex, intestinal secretions, and gastrointestinal motility. **Public Comment:** None. **Committee Discussion:** None. Dr. Wallace moved to approve. Dr. Gill seconded the motion. The motion carried unanimously.

Item	Notes
ii. Beta2-Agonist – Long-Acting/Anticholinergics Agents – Class Review – New Drugs to Existing Class - New Agent: (Duaklir® Pressair®)	**Background:** This class was last reviewed in March of 2017 for inclusion of Bevespi Aerosphere™, and also includes Anoro Ellipta®, Stiolto® Respimat®, and Utibron™ Neohaler®. Duaklir® Pressair® is composed of aclidinium bromide and formoterol fumarate. These agents relax bronchial smooth muscle and cause bronchodilation. **Public Comment:** None. **Committee Discussion:** None. Dr. Haneke moved to approve. Dr. Gill seconded the motion. The motion carried unanimously.
iii. Immunomodulation Agents – Adult Rheumatoid Arthritis – Class Review – New Drugs to Existing Class - New Agents: (Abrilada®, Amjevita™, Avsola®, Cyltezo®, Erelzi®, Eticovo®, Hadlima™, Rinvoq™)	**Background:** This class was last updated in September 2018 for the inclusion of Olumiant® and currently includes Actemra®, Cimzia®, Enbrel®, Humira®, Inflectr®a, Kevvzara®, Kineret®, Orencia®, Remicade®, Renflexis®, Rituxan®, Simponi®, Simboni Aria®, Xeljanz®, and Xeljanz® XR. Biosimilar products Abrilada ® (adalimumab-afzb), Amjevita™ (adalimumab-atto), Cyltezo® (adalimumab-adbm), and Hadlima™ (adalimumab-bwwd) were approved for multiple indications of Humira® (adalimumab). Erelzi® (etanercept-szzs) and Eticovo® (etanercept-ykro) are biosimilar products to Enbrel® (etanercept) and were also approved for all of its indications. Avsola® (infliximab-axxq), a biosimilar product to Remicade® (infliximab), was approved for Adult Rheumatoid Arthritis. All five of these new medications inhibit Tumor Necrosis Factor (TNF). Rinvoq™ (rituximab), was also approved for Adult Rheumatoid Arthritis. **Public Comment:** Jim Baumann from Pfizer- indications for biosimilars do not always match indications for reference product. Truxima®, since removed from this list of agents, was provided as an example.

Item	Notes
	Dave Miley from Teva – clarified on Truxima® that while it is currently indicated, the manufacturer is not able to promote due to a patent settlement. The Package Inserts for medications reflect the marketable indications rather than FDA approved indications. Dr. Wallace moved to strike Truxima® from the list for this class. Dr. Haneke seconded the motion. The motion carried unanimously. **Committee Discussion:** None. Dr. Wallace moved to approve this item with the above change. Dr. Grimsley seconded. The motion carried unanimously.
iv. Immunomodulation Agents – Ankylosing Spondylitis – Class Review –New Drugs to Existing Class - New Agents: (Abrilada®, Amjevita™, Avsola®, Cyltezo®, Erelzi®, Eticovo®, Hadlima™	**Background:** This class was last reviewed in December 2017 for the inclusion of Cimzia® and currently includes Cosentyx®, Enbre® l, Humira®, Inflectra®, Remicade®, Renflexis®, and Simponi®. Biosimilar products Abrilada® (adalimumab-afzb), Amjevita™ (adalimumab-atto), Cyltezo® (adalimumab-adbm), and Hadlima™ (adalimumab-bwwd) were approved for multiple indications of Humira® (adalimumab). Erelzi® (etanercept-szzs) and Eticov® o (etanercept-ykro), biosimilar products to Enbrel® (etanercept), were also approved for all of its indications. Avsola® (infliximab-axxq), a biosimilar product to Remicade® (infliximab), was also approved for Ankylosing Spondylitis. Simponi Aria® is the IV formulation of Simponi® with the same indications except for ulcerative colitis. All eight of these new medications inhibit Tumor Necrosis Factor (TNF). **Public Comment:** None. **Committee Discussion:** None. Dr. Wallace moved to approve.

Item	Notes
	Dr. Pankey seconded the motion. The motion was carried unanimously.
v. Immunomodulation Agents – Crohn's Disease – Class Review – New Drugs to Existing Class – New Agents: (Abrilada®, Amjevita™, Avsola®, Cyltezo®, Hadlima™)	**Background:** This class was last reviewed in March 2017 for the inclusion of Stelara® and Entyvio®. The class currently includes Cimzia®, Humira®, Inflectra®, Remicade®, Renflexis®, Tysabr®i, and the two mentioned previously. Biosimilar products Abrilada® (adalimumab-afzb), Amjevita™ (adalimumab-atto), Cyltezo® (adalimumab-adbm), and Hadlima™ (adalimumab-bwwd) were approved for multiple indications of Humira® (adalimumab). Avsola® (infliximab-axxq), a biosimilar product to Remicade® (infliximab), was also approved for Adult Crohn's Disease. All five of these new medications inhibit Tumor Necrosis Factor (TNF). **Public Comment:** None. **Committee Discussion:** None. Dr. Gill moved to approve. Dr. Haneke seconded the motion. The motion carried unanimously.

Item	Notes
vi. Immunomodulation Agents – Juvenile Idiopathic Arthritis – Class Review – New Drugs to Existing Class – New Agents: (Abrilada®, Amjevita™, Cyltezo®, Erelzi®, Eticovo®, Hadlima™)	**Background:** This class was last reviewed in June 2018 for inclusion of Ilaris® and currently includes Actemra®, Enbrel®, Humira®, and Orencia®. Abrilada® (adalimumab-afzb), Amjevita™ (adalimumab-atto), Cyltezo® (adalimumab-adbm), and Hadlima™ (adalimumab-bwwd) were approved for multiple indications of Humira® (adalimumab). Erelzi® (etanercept-szzs) and Eticov® (etanercept-ykro), biosimilar products to Enbrel® (etanercept), were also approved for all of its indications. **Public Comment:** None. **Committee Discussion:** None. Dr. Haneke moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.
vii. Immunomodulation Agents – Plaque Psoriasis – Class Review – New Drugs to Existing Class - New Agents: (Abrilada®, Amjevita™, Avsola®, Cyltezo®, Erelzi®, Eticovo®, Hadlima™, Skyrizi™)	**Background:** This class was last reviewed in June 2018 for the inclusion of Ilumya® and currently includes Amevive®, Cosentyx®, Enbrel®, Humira®, Inflectra®, Otezla®, Remicade®, Renflexis®, Siliz®, Stelara®, Taltz®, and Tremfya®. Biosimilar products ®. Abrilada® (adalimumab-afzb), Amjevita™ (adalimumab-atto), Cyltezo® (adalimumab-adbm), and Hadlima™ (adalimumab-bwwd) were approved for multiple indications of Humira® (adalimumab). Erelzi® (etanercept-szzs) and Eticov® o (etanercept-ykro), biosimilar products to Enbrel® (etanercept), were also approved for all of its indications. Avsola® (infliximab-axxq), a biosimilar product to Remicade® (infliximab), was also approved for Plaque Psoriasis. All five of these new medications inhibit Tumor Necrosis Factor. Skyrizia™ (risankizumab-rzaa) is a monoclonal antibody that targets IL-23 (similar to Ilumya) and was also approved. **Public Comment:** None. **Committee Discussion:** None. Dr. Gill moved to approve.

Item	Notes
	Dr. Pankey seconded the motion. The motion carried unanimously.
viii. Immunomodulation Agents – Psoriatic Arthritis – Class Review – New Drugs to Existing Class – New Agents: (Abrilada®, Amjevita™, Avsola®, Cyltezo®, Erelzi®, Eticovo®, Hadlima™, Simponi Aria ®)	**Background:** This class was last reviewed in March 2018 for the addition of Taltz, Xeljanz, and Xeljanz XR. Biosimilar products Abrilada®, Amjevita™, Cyltezo®, and Hadlima™ were approved for multiple indications of Humira®. Erelzi® and Eticov®, biosimilar products to Enbrel®, were also approved for all its indications. Avsola®, a biosimilar product to Remicade®, was also approved for Psoriatic Arthritis. Simponi Aria® is the IV formulation of Simponi® with the same indications except for ulcerative colitis. **Public Comment:** None. **Committee Discussion:** None. Dr. Wallace moved to approve. Dr. Haneke seconded the motion. The motion carried unanimously.

Item	Notes
ix. Immunomodulation Agents – Ulcerative Colitis – Class Review – New Drug to Existing Class – New Agents: (Abrilada®, Amjevita™, Avsola®, Cyltezo®, Hadlima™, Stelara®, Xeljanz® XR)	**Background:** This class was last updated in September 2018 for the inclusion of Xeljanz® and currently includes Entyvio®, Humira®, Inflectra®, Remicade®, Renflexis®, and Simponi®. Biosimilar products Abrilada® (adalimumab-afzb), Amjevita™ (adalimumab-atto), Cyltezo® (adalimumab-adbm), and Hadlima™ (adalimumab-bwwd) were approved for multiple indications of Humira® (adalimumab). Avsola® (infliximab-axxq), a biosimilar product to Remicade® (infliximab), was also approved for Ulcerative Cholitis. All five of these new medications inhibit Tumor Necrosis Factor (TNF). Xeljanz® XR is the extended-release form of Xeljanz®, both of which are JAK inhibitors. Stelara® is an IL-12 and IL-23 antagonist. **Public Comment:** None. **Committee Discussion:** None. Dr. Wallace moved to approve. Dr. Pankey seconded the motion. The motion carried unanimously.
x. Approval to add biosimilars for the same indication(s) as the reference product in the Consent Agenda Item approval process.	**Background:** Approval to add biosimilars for the same indication(s) as the reference product in the Consent Agenda Item approval process. **Public Comment:** Rob Hansen from Pfizer recommended a language change to read "…biosimilars for FDA approved indication(s)..." rather than "…same indication(s)…" **Committee Discussion:** None. Dr. Wallace moved to approve, with the above change. Dr. Gill seconded the motion. The motion carried unanimously.

Item	Notes
V. Open Public Comment	Ms. Grant updated the committee regarding previous requests: - Requested changes to the 90-day maintenance medications list. See the KMAP bulletin for details. - Requested changes to nebulized formulations be moved to preferred: Most were already preferred; others addressed. See PDL list on website for updates. - PA for acne medications: The clinical PA for acne was discontinued, to allow only the PDL process to manage access. See the KDHE Pharmacy website link below. https://www.kdheks.gov/hcf/pharmacy/default.htm Ms. Grant also shared a communication opportunity for providers to share comments or suggestions. Email address: kdhe.MedicaidPharmacyQuestions@kdhe.ks.gov
VI. Adjourn	Dr. Wallace moved to adjourn. Dr. Gill seconded the motion. Dr. Sweet adjourned the meeting at 12:10 p.m.

APPENDIX A

March 2020 Consent Agenda Item List				
This PDL option/process was approved 09/13/2017 by the PDL Committee and 10/11/2017 by the DUR Board. The Extended Consent Agenda was approved at the March 2019 PDL Committee meeting and the April 2019 DUR Board meeting.				
Drug Proposed - Consent Agenda Item	**Compare Drug**	**Supporting information**	**Meeting Date listed on the PDL Agenda**	**PDL Committee Approval Yes/No**
Arazlo™ Lotion	Tazorac® Cream/Gel		3/11/2020	Yes
Conjupri® Tablets	Norvasc® Tablets		3/11/2020	Yes
Drizalma Sprinkle®	Cymbalta®		3/11/2020	Yes
Harvoni® Pellets	Harvoni® Tabs		3/11/2020	Yes
Ipratropium Bromide Inh Sol	Atrovent® HFA		3/11/2020	Yes
ProAir Digihaler®	ProAir HFA®		3/11/2020	Yes
RediTrex™ Injection	Rasuvo® Injection		3/11/2020	Yes
Riomet ER ™ Suspension	Riomet® Solution		3/11/2020	Yes
Solvaldi® Pellets	Sovaldi® Tabs		3/11/2020	Yes
Zyrtec ODT/CT®	Zyrtec® Tabs		3/11/2020	Yes